APR 19 2011

K093581

GE Healthcare

3000 N. Grandview Blvd.
Waukesha, WI 53188

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date Prepared: March 30, 2011

Submitter: GE Healthcare (GE Medical Systems, LLC)
3000 N. Grandview Blvd., W-1140
Waukesha, WI 53188

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DEVICE IDENTIFICATION

Trade Name: Discovery CT590 RT and
Optima CT580

Common/Usual Name: Discovery CT590 RT and
Optima CT580 RT and Optima CT580 W

Classification Name: Computed Tomography X-ray System per
21CFR892.1750

Product Code: 90-JAK

Predicate Device(s): GE LightSpeed RT^{16} / Xtra CT System (K082104)

Manufacturer(s): GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

GE Hangwei Medical Systems Co., Ltd
No. 2 North Yong Chang North Street
Beijing Economy & Technology Development Zone
Beijing, 100176, China

Distributor: Same as Manufacturer

Marketed Devices: The Discovery CT590 RT and Optima CT580 series of systems are of comparable type and substantially equivalent to GE Healthcare's currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards. In addition the system complies with the same or equivalent standards and has similar indications for use and intended use.

DEVICE DESCRIPTION

The Discovery CT590 RT and Optima CT580 series of systems are composed of a gantry, patient table, operator console, computer, power distribution unit (PDU) and includes image acquisition hardware, image acquisition and reconstruction software, associated accessories and connections/interfaces to accessories. The Discovery CT590 RT and Optima CT580 series of systems is an evolutionary modification to the LightSpeed RT^{16} / Xtra V2 CT systems (K082104). It is developed from the hardware platform of the LightSpeed RT^{16} / Xtra V2 systems by adding new application features, modifications in design that involve changes in hardware, software, firmware, and recon.

The Discovery CT590 RT and Optima CT580 series of systems are designed to be a head and whole body CT system incorporating the same basic fundamental operating principles and similar indications for use. Materials and construction are equivalent to our existing marketed products, which are compliant with UL 60601-1, IEC 60601-1 and associated collateral and particular standards, and 21CFR Subchapter J.

INDICATIONS FOR USE

The Discovery CT590 RT and Optima CT580 series of Computed Tomography systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), and Gated (Respiratory and Cardiac)

acquisitions in patients of all ages. These images may be obtained either with or without contrast. These devices may include signal analysis and display equipment, patient and equipment supports, components and accessories.

These devices may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.

The GE Discovery CT590 RT and Optima CT580 series of Computed Tomography systems are intended for head, whole body, and vascular X-ray Computed Tomography applications in patients of all ages.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

The systems are capable of assisting with minimally invasive procedures such as biopsy and ablation of tumors and pathology. The system allows imaging of Bariatrics patients, up to and including the morbidly obese population (BMI > 40).

The systems can acquire CT anatomical images that are clinically useful in the simulation and planning of radiation therapy for the treatment of cancer.

COMPARISON WITH PREDICATE

The Discovery CT590 RT and Optima CT580 series of systems were developed from the hardware platform of the LightSpeed RT^{16} / Xtra V2 CT systems (K082104). It involves changes from the LightSpeed RT^{16} / Xtra V2 CT systems to add new application features, modification in design that involve changes in hardware, software, firmware, and recon.

The Discovery CT590 RT and Optima CT580 series of systems uses virtually the same materials, identical operating principles as our existing marketed product, and has the same indications for use as our existing marketed product, LightSpeed RT^{16} / Xtra V2 CT systems. We believe the Discovery CT590 RT and Optima CT580 series of systems are of comparable type and substantially equivalent to our currently marketed system listed above and complies with the same standards, and has similar intended uses.

The Discovery CT590 RT and Optima CT580 series of systems complies with the X-ray requirements of 21CFR1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards.

ADVERSE EFFECTS ON HEALTH

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (UL/CSA and IEC).
- Compliance to applicable CDRH 21 CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21 CFR 820.

CONCLUSION

The Discovery CT590 RT and Optima CT580 series of systems is an evolutionary modification to the LightSpeed RT[16] / Xtra V2 CT systems (K082104). It does not result in any new potential safety risks and performs as well as or better than devices currently on the market. The Discovery CT590 RT and Optima CT580 series of systems will be certified to comply with the X-ray requirements of 21CFR 1020.30 and 1020.33, as well as the safety requirements of UL 60601-1, and IEC 60601-1 and associated collateral and particular standards. GE Healthcare considers the Discovery CT590 RT and Optima CT580 series of systems to be equivalent to other marketed devices with similar indications for use and meeting same standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. John Jaeckle
Regulatory Affairs Manager – MI & CT
GE Medical System LLC (GE Healthcare)
3000 N. Grandview Blvd., W-1140
WAUKESHA WI 53188

APR 19 2011

Re: K093581
Trade/Device Name: Discovery CT590 RT and Optima CT580
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 30, 2010
Received: March 31, 2010

Dear Mr. Jaeckle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093581

Device Name: Discovery CT590 RT and Optima CT580

Indications for Use:

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for Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093581

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)